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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,020	02/23/2004	John Kevin Collins	P66879US3	3753
136	7590	12/06/2005	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,020	COLLINS ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-134 is/are pending in the application.
- 4a) Of the above claim(s) 89-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I (claims 56-88) in the reply filed on 10/25/2005 is acknowledged. The traversal is on the ground(s) that several groups of claims are not drawn to distinct inventions because they include essential features of *Bifidobacterium* strain that posses immunomodulatory activities. This is not found particularly persuasive because claims are different in breath or in scope as presently claimed and the intended "essential" features are differently claimed. Moreover, applicants appear to admit that definitions are different for various claimed products of the present invention (response pages 2-3). Applicants also argue that all product claims were grouped as one invention in the parent applications. However, claims in parent applications were presented in a different form having varying breath and scope. Furthermore, the references that would be applied to one product would not necessarily anticipate or render obvious the other product due to the scope differences present in the instant claims regardless the "essential" feature(s) of *Bifidobacterium* strain as it might be intended. Thus, there is a burden of search. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group of claimed products. Thus, the requirement is still deemed proper and, therefore, is made FINAL.

Claims 89-134 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention(s).

Claims 56-88 are under examination in the instant office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications 99 0033 and 990782 filed in Ireland on 1/15/199 and 9/20/1999 respectively. It is noted, however, that applicant has not filed certified copies of these applications as required by 35 U.S.C. 119(b).

Information Disclosure Statement

1. The information disclosure statement filed 7/27/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The Form PTO 1449 is placed in the application file, but the information referred to therein has not been considered in the lack of copies of foreign patent documents and non-patent references.
2. Both information disclosure statements filed on 2/23/2004 fail to comply with 37 CFR 1.98(a)(1), which requires the following: the application number of the instant application in which the information disclosure statement is being submitted on each page of the list. All Forms including Form 1449 and Form 892 indicate number of the other application. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. Furthermore, the information referred to therein cannot be considered in the lack of copies of foreign patent documents and non-patent references in the instant application being in the IFW format.

Specification

The disclosure is objected to because of the following informalities:

The preliminary amendment to specification filed 12/30/2004 appears to contain some typing errors in the original designation of strains. The as-filed specification indicates strains as UCC 35624 and UCC 188. The amendment filed 12/30/2004 recites "HCC" in place of "UCC".

Appropriate correction or clarification is required.

Claim Objections

Claims 56-88 are objected to because of the following informalities:

The Latin name should be italicized in claims 56 and 60, if the claimed term "Bifidobacterium" is intended for representatives of a biological genus of *Bifidobacterium*.

Appropriate correction and/or clarification are required.

Claim Rejections - 35 USC § 112

Deposit

Claims 56-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

All claims and at least some of the claims require one of ordinary skill in the art to have access to specific microorganisms strain UCC 35624 (NCIMB 41003) and *Lactobacillus salivaricus* UCC 118 (NCIMB 40829) respectively.

The claimed strains are said to be deposited in the National Collections of Industrial and Marine Bacteria Limited (NCIMB) (see specification page 6 and page 8) that has acquired the

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status of an International Depository in accordance to the Budapest Treaty. A declaration stating that all restrictions related to the strains deposited in NCIMB will be irrevocably removed upon issuance of the patent has been submitted (papers filed 12/30/2004). However, due to the typing errors occurred in the original designations of strains (“HCC” in amendment and in declaration; “UCC” in specification, “NFBC” in deposit receipts from NCIMB), the deposit issues and requirements are not fully satisfied. Please, provide clarifications and/or appropriate corrections related to original designations of claimed strains.

Indefinite

Claims 70, 81 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 recites the use of a “genetically modified mutant” of *Lactobacillus* strain UCC 118 in combination with the claimed *Bifidobacterium* strain. But it is unclear what genetic modification is intended in the lack of specific definitions in the as-filed specification.

Claims 88 and 83 recite the use of some additional “bacterial component” and “bacterial compound” respectively. But it is unclear what bacterial cells and/or extracts are intended in combination with the claimed bacterial strain in the lack of specific definitions in the as-filed specification.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 56-62 and 72-88 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,077,504 (Cavaliere et al.).

Claims are directed to a bacterial strain NCIMB 41003 (UCC 35624) belonging to the genus of *Bifidobacterium*. Some claims are further drawn to the strain in a form of viable or non-viable cells. Some claims are further drawn to the formulations comprising the claimed strain belonging to the genus of *Bifidobacterium* and various pharmaceutical carriers or food products including milk, yogurt, etc. or prebiotics. Some claims are further drawn to the formulations comprising the claimed strain belonging to the genus of *Bifidobacterium* in amounts more than 10x6 cfu per gram of the formulation. Some claims are further drawn to the formulations comprising the claimed strain belonging to the genus of *Bifidobacterium* and other probiotics and/or bacterial components.

US 6,077,504 discloses bacterial strains *Bifidobacterium longum* ATCC 15707 and *Bifidobacterium infantis* ATCC 15697 (table 1) wherein these strains have immunomodulatory effects upon oral consumption (col. 4, lines 25-26 and/or lines 60-66; col. 8, line 54). Further, the cited patent US 6,077,504 teaches that these bacterial stains protect against pathogenic microorganisms (col. 8, line 51) and, thus, they inhibits growth of Gram positive and/or Gram negative bacteria as required by the claimed invention. The cited patent US 6,077,504 teaches

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that these stains improve clinical conditions of diseased patients and/or they provide immunomodulatory effects in systems comprising gastrointestinal tract epithelial cells and immune cells or lymphocytes (col. 9, lines 58-66). The cited patent US 6,077,504 teaches that these stains reduce tendency to diarrhea (col. 4, line 27). The cited patent also teaches pharmaceutical and/or food formulations with bacterial strains belonging to *Bifidobacterium sp.* wherein bacterial cells are present in amounts more than 10^6 cfu per gram of the formulation (col. 4, lines 36-39) as required by the claimed invention. The cited patent teaches incorporation of other probiotics and/or bacterial components, for example: lactic bacteria belonging to *Streptococcus thermophilus*, (col. 4, line 33) into formulations with bacterial strains belonging to *Bifidobacterium sp.* The cited patent teaches incorporation of prebiotics, drugs and/or bacterial components, for example: oligosaccharides, anti-inflammatory drugs, vitamins and amino-acids (col. 5, lines 50-55). The cited patent teaches incorporation of bacterial strains into liquid, creamy or pasty foodstuff (col. 7, lines 50-55; col. 8, lines 15-25).

The cited patent US 6,077,504 is considered to anticipate the claims invention because it teaches identical bacterial strain(s) and compositions with these strains wherein the strains belong to the genus of *Bifidobacterium* including strains *Bifidobacterium longum* ATCC 15707 and *Bifidobacterium infantis* ATCC 15697 which are characterized by identical essential features and/or effects including immunomodulation and protection from pathogens as the claimed strain/composition. Consequently, the claimed strain/formulation with the strain UCC 35624 belonging to *Bifidobacterium sp.* appears to be anticipated by the cited documents.

In the alternative, even if the claimed strain UCC 35624 is not identical to the referenced strains with regard to some unidentified characteristics, the differences between that which is

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disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely inherently possess the same characteristics of the claimed strain UCC 35624 particularly in view of the similar characteristics which they have been shown to share such as assignment to the same genus and capability of producing immunomodulatory and antimicrobial effects. Thus, the claimed strain UCC 36624 and formulations with this strain would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

2. Claims 56-62 and 72-88 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,368,591 (Chen et al.)

Claims as explained above.

US 6,368,591 disclose the strain belonging to the genus of *Bifidobacterium* including strain *Bifidobacterium longum* strain 6-1 (CCTCC number M 98004) which inhibits growth of Gram positive and/or Gram negative bacteria including *Staphylococcus sp.* and coliforms (col. 6, lines 56-58), which is a gastrointestinal bacteria (col. 4, lines 61-640, which produces immunomodulatory effects upon oral consumption or regulates immunologic function, decreases abnormal level of cytokine expression (col. 14, lines 43-60), which is effective in treating inflammation including diarrhea (col. 14, line 31). The cited patent US 6,368,591 also teaches various pharmaceutical and food formulation comprising strain *Bifidobacterium* in amounts more than 10x6 cfu/g including cells in viable form and in non-viable form after some period of storage (table 2) together with additional health beneficial probiotic lactobacteria (col. 9, lines

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33-36), pharmaceutical carriers, food additives or products including milk, glutamate, vitamins, etc. or prebiotics (col. 9, lines 43-56).

The cited patent US 6,368,591 is considered to anticipate the claimed invention because it teaches identical bacterial strain and composition with this strain wherein the strain belongs to the genus of *Bifidobacterium* and, thus, characterized by identical essential features and/or effects. In the alternative, even if the claimed strain UCC 35624 is not identical to the referenced strains with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely inherently possess the same characteristics of the claimed strain UCC 35624 particularly in view of the similar characteristics which they have been shown to share such as assignment to the same genus and capability of producing immunomodulatory and antimicrobial effects. Thus, the claimed strain UCC 36624 and formulations with this strain would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,077,504 (Cavaliere et al.) and/or US 6,368,591 (Chen et al.) taken with WO 98/35014.

Claims 56-62 and 72-88 as explained above. Claims 63-71 are further drawn to incorporation of *Lactobacillus salivaricus* including particular strain NCIMB 40829 (UCC 118) into formulations with *Bifidobacterium* strain NCIMB 41003 (UCC 35624).

The cited documents US 6,077,504 and US 6,368,591 disclose the strains of *Bifidobacterium* having immunomodulatory effects and the formulations comprising the strains of *Bifidobacterium* together with additional probiotic cultures including lactobacteria having similar immunomodulatory effects. But they are lacking particular disclosure related to the use of *Lactobacillus* or *Lactobacillus salivaricus* including particular strain UCC 118 as an additional probiotic lactobacteria in composition with the strains of *Bifidobacterium*.

However, the cited patent WO 98/35014 teaches *Lactobacillus* or *Lactobacillus salivaricus* including particular strain UCC 118 and it suggests incorporation of this strain into the health promoting formulations/compositions.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute or to add the strain belonging to *Lactobacillus* or *Lactobacillus salivaricus* including particular strain UCC 118 of the cited patent WO 98/35014 for/to the additional probiotic lactobacteria in the compositions with the strains belonging to *Bifidobacterium* taught by the cited documents US 6,077,504 and/or US 6,368,591 with a reasonable expectation of success in obtaining the health promoting formulations/compositions with immunomodulatory effects because it is known that lactobacteria and bifidobacteria produce various health beneficial effects including the immunomodulatory effects and it is also well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition

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which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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December 1, 2005



VERA AFREMOVA

PRIMARY EXAMINER